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## Research Article

# Accounting for Technical, Ethical, and Political Factors in Priority Setting

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**Abstract**—This article investigates two cases of priority setting to explore how, in addition to technical considerations, ethical and political factors shape the allocation of health resources. First, we discuss how Thai authorities adjudicated a coverage decision for HLA-B\*1502 screening, which meets the national cost-effectiveness threshold for only some of the conditions it can detect. Second, we consider England's Cancer Drugs Fund to investigate the interplay of technical decision making and political reality. Our findings suggest four concluding observations for policy makers and others considering priority-setting processes. First, we observe that different methods can produce conflicting recommendations, which makes priority setting very complex. Second, we suggest that robust processes for generating and weighing political, ethical, and technical evidence are essential because there is no absolute standard by which resource allocation decisions can be made. Third, priority setting is inherently political, and improving its technical and ethical validity means constructing political importance for these other factors. Fourth, we argue that transparency in the trade-offs required to set priorities is important ethically and can help build support politically.

**Keywords:** HLA-B\*1502 screening, Cancer Drugs Fund, ethics, politics, priority setting

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## INTRODUCTION

Priority setting in health involves decisions about who gets what, when, and how, to paraphrase Lasswell's definition of politics.<sup>1</sup> It is a contested process because the demand for services is unlimited and resources are finite. Priorities have to be set that reflect health needs, economic resources, professional and societal values, and political considerations. This formulation follows the categories of technical, ethical, and political developed by Roberts et al. for the analysis of health reform.<sup>2</sup> Setting priorities is a difficult task that

concerns policy makers whether they are looking to introduce efficiency savings or policies to advance universal health coverage (UHC). Priority setting includes highly technical processes such as the calculation of quality-adjusted life years (QALYs), incremental cost effectiveness ratios (ICERs), and other health economic measures. Priority-setting processes are not purely technical, though—they give rise to ethical dilemmas and are subject to political influences, as well.<sup>3</sup> However, it is unclear how these factors might be accounted for institutionally, especially in low- or middle-income countries considering how to build priority-setting institutions. Ethical frameworks developed in high-income countries over the last decades represent attempts to systematically guide decision making, and these would seem to be a sound starting point. In contrast, how best to account for political factors in priority-setting processes remains a more elusive endeavor and a relatively underresearched area, despite contributions on specific cases and methods of analysis.<sup>4-7</sup>

We address the following question: What can we learn about managing the priority-setting process from two cases in which ethical and political factors shaped the ultimate decisions on how to allocate health resources? We begin by providing a brief overview of the literature on the technical, ethical, and political aspects of priority setting. This is followed by an introduction to the two cases discussed in this article, namely, the screening for HLA-B\*1502 as a biomarker for severe hypersensitivity induced by carbamazepine in Thailand and the establishment of the Cancer Drugs Fund (CDF) in England. Finally, we discuss the two case studies and offer four lessons for policy makers and others considering priority-setting processes.

## TECHNICAL APPROACHES TO PRIORITY SETTING IN HEALTH

Priority setting refers “[...] to the allocation of resources in health care both in terms of the relative priority to be attached to different demands and needs and to decisions that are made not to fund treatment.”<sup>8</sup> In many cases, such decisions are informed by technical approaches, such as cost-effectiveness analyses or evidence-based clinical guidelines. Among many examples, Thailand and England have established institutional bodies with a mandate to conduct (or contract for) such technical analyses to inform decision-making on what is included in or excluded from the health benefit basket. In this trend toward decision making based on technology appraisals, “[...] pharmaceutical products are the

main—but by no means the only—subjects of such appraisals.”<sup>9</sup>

“Technical” approaches or “technical” institutions are referred to as such because they are concerned primarily with bringing technical analysis to bear on policy decisions, although we recognize that both reflect many factors, including political and ethical ones. For instance, the decision to establish technical bodies is made through political processes, whether parliamentary or executive, and some are explicitly charged with considering social values.<sup>10</sup> Considering many forms of evidence and analysis is important because very commonly data are insufficient or evidence is difficult to interpret.<sup>11</sup> Further, the interpretation of technical evidence is partly a social process: the same randomized controlled trial evidence is interpreted differently depending on different national paradigms.<sup>12</sup>

## THE ETHICS OF PRIORITY SETTING

Priority setting concerns the distribution of health benefits and burdens in society. That this is also an ethical issue was recognized early among ethicists who, inspired by theories of distributive justice, explored how to meet health needs fairly.<sup>13-15</sup> Others emphasized the motivation for health maximization.<sup>16,17</sup>

### Ethical Principles for Priority Setting

Despite some disagreement between different theoretical frameworks, some consensus has emerged during the last decades over what kinds of ethical considerations are relevant (Box 1). First, there is general agreement that priority setting should be impartial; that is, unprejudiced and unbiased. Every citizen should be treated with equal respect and dignity. Second, the formal principle of equality—treating equals as equals—always applies. This formal principle can take two forms: people who are equal in all relevant respects should be treated equally (horizontal equity), and people who are unequal in the relevant respects should be treated unequally (vertical equity). The formal principle of equality is a standard against which any clinical or political decision could be measured. If two patient groups are equal on all relevant criteria, they are treated unequally if one group is given priority over the other.<sup>18</sup> This often happens in practice but is nevertheless ethically unacceptable. Third, there is broad agreement that priority setting should aim at both fair distribution and health maximization.<sup>19</sup>

### Ethical Criteria for Priority Setting

There is, among ethical theories of priority setting, overlapping consensus on a set of three relevant criteria (Box 1). If some service or policy is documented as effective, the magnitude of the health effect is relevant under both a distributive and a maximizing principle. One widely accepted measure of effectiveness is healthy life years (using quality-adjusted life years or disability-adjusted life years). The cost of the service in question is also always relevant. Decision makers need to know whether an alternative use of resources could lead to a more fair or more efficient distribution. A third criterion, severity of disease—or, simply, health without the service—is seen as necessary and relevant only under the principle of fair distribution. This is relevant because decision makers need information about who is worse off if a service is not given priority. The health maximization principle does not consider who is worse off; instead, only aggregate benefit matters. However, many ethicists agree that both fair distribution and health maximization matter and therefore that all three criteria are relevant.<sup>19,20</sup>

It is also possible, and indeed obligatory, to take non-health benefits and burdens into consideration when setting priorities. In the context of low- and middle-income countries, a fourth relevant criterion, financial risk protection, has been widely discussed and accepted.<sup>21</sup>

There is also some agreement among ethical theories about irrelevant criteria for priority setting. Even if contravened in practice, it is not considered acceptable to treat people differently according to their gender, race, ethnicity, religion, sexual orientation, or social status. However, there is still substantial disagreement about the relevance of contested criteria, including age, responsibility for own health, area of living, and personal income.<sup>a</sup>

### Making Ethical Judgments

Evaluating priority setting against ethical principles requires information, analysis, judgment, and the use of public reason. In the case of so-called horizontal equity, this can be quite straightforward (see Box 1).

Though making ethical judgments using the outlined criteria can be straightforward in some cases, it is more complex in others. Reasonable people agree on much but may disagree about when people are unequal in the relevant sense or about which criteria are relevant and how they should be interpreted, applied, and weighted.<sup>22</sup> Some therefore argue that substantive evaluation of priority-setting decisions should be replaced by assessments according to criteria for fair and legitimate process.<sup>23</sup> Others argue that both process

and substantive judgments are important, a viewpoint with which the present authors agree.<sup>24</sup> Accountability for reasonableness is one widely accepted framework that sets out conditions for legitimate process.<sup>25</sup> The core idea is that reasons for priority-setting decisions should be publicly available. This means that those who provide and pay for services should make the range of services they offer public and that the reasons for inclusion or exclusion are made clear to all key stakeholders, assuming that all seek reasonable justifications for such decisions. More specifically, accountability for reasonableness suggests four conditions that should be met: publicity, relevance, revision and appeals, and regulation. Priority setting should be publicly justified with reference to relevant reasons and evidence. A fair process should be inclusive with broad stakeholder involvement and mechanisms for critical assessment and revision. The process itself should be institutionalized so that all key decisions meet these conditions. If satisfied, these four conditions can connect decisions about priority setting to broader educative and deliberative democratic processes.<sup>26</sup>

In summary, priority setting affects the distribution of health benefits and burdens in society. Even if there is some disagreement between ethical theories about specific issues, there is wide support for and no discernable disagreement in the relevant ethics literature that priority setting should be impartial, treat people as equals, and follow from clearly relevant and agreed criteria. Most theories also promote fair distribution and health maximization as key principles. Both substantive and procedural criteria can be used to evaluate and criticize priority-setting decisions.

### THE POLITICS OF PRIORITY SETTING

In addition to the technical approaches and ethical frameworks, the literature on the political aspects of priority setting provides analytical lenses that help examine political forces. Against the background of one prominent definition of politics as the study of who gets what, when, and how,<sup>1</sup> priority setting can be viewed as fundamentally political because of its distributional consequences. This view is supported by many studies examining the political nature of priority setting and health reform<sup>2,3,5-7,27-32</sup> and the evaluation of the Oregon Health Plan.<sup>29</sup>

In what ways is priority setting fundamentally political? First and foremost it arises as a policy response to the universal challenge of building and sustaining high-quality health care systems that are constrained by national fiscal space but charged with satisfying demand that often expands and is very hard to reduce. Second, it is political because policy

## Box 1 Ethical Aspects of Priority Setting

### Key principles

1. Priority setting should be impartial, unprejudiced, and unbiased
2. The formal principle of equal treatment
  - People who are equal in all relevant respects should be treated equally (horizontal equity)<sup>1</sup>, and
  - People who are unequal in the relevant respects should be treated unequally (vertical equity)
3. Priority setting should aim at both fair distribution and health maximization

### Relevant criteria for priority setting

- Magnitude of health effect
- Alternative cost
- Health without the service in question (severity of disease)
- Financial risk protection

### Irrelevant criteria

- Gender
- Race
- Ethnicity
- Religion
- Sexual orientation
- Social status

### Contested criteria

- Age
- Responsibility for own health
- Area of living
- Personal income

<sup>1</sup>If two patient groups are equal on all relevant criteria – they have the same health if not treated, the expected outcomes are the same, and service costs are the same – they are treated unequally if one group is given higher priority, say because of ethnicity. In cases of vertical equity, when people are unequal in a relevant sense, the judgments become more complex. But even here, the overlapping consensus offers advice. For example, if we consider a given case, where two groups have the same health status without the service, and the same expected outcomes, but alternative costs differ widely – most ethical theories of distributive justice in health will accept that the more cost-effective service is given priority. This is so because the two groups differ in one relevant sense and in no other. The two groups are treated differently for the right reason. Similarly, if two groups are similar with respect to cost-effectiveness of the service they need, but differ in health without this service, say the first group has multiple sclerosis and average healthy life expectancy is lower than for a group with, say, influenza, vertical equity implies that the former service should have priority.

makers must balance competing needs and interests between different groups and stakeholders at societal and government levels. For example, economic interests might demand policies that strengthen the pharmaceutical sector as a provider of employment opportunities and an investor in research and development, but these policies may be at odds with the

individual and societal interest in limiting drug expenditures and increasing access.<sup>33</sup>

Priority-setting outcomes that are viewed negatively by certain groups are often opposed through political processes, whether in the public eye or behind the scenes. Commonly, advocacy groups have contested decisions from the National Institute for Health and Care Excellence (NICE) and lobbied English policy makers by framing issues in emotional and ethical terms. For example, in 2008 NICE decided not to recommend kidney cancer medicines it had found to be cost ineffective; this was contested with the slogan that kidney cancer patients “deserved the right to life.”<sup>34</sup>

Third, priority setting involves many actors,<sup>2,3</sup> at many different levels of decision making.<sup>35</sup> This implies that even the most transparently designed and technically sound priority-setting processes are inputs into larger political processes that involve complex relationships between actors and reflect the contested political economy of health. Even priority-setting institutions designed to moderate political pressures by basing decision making on economic analyses and transparent processes consist of complex political processes involving many stakeholders who may hold different values and worldviews. Finally, like other policy areas, health policy is subject to the results of election cycles, changing government priorities, and economic trends.

In the triad of technical, ethical, and political judgments that comprise priority setting,<sup>2</sup> the technical and ethical aspects appear easier to navigate as methods and frameworks to aid decision makers have been developed. By comparison, the question how to navigate the political forces of priority setting appears more challenging because such forces can have greater power than even the strongest institutions, are subject to internal and external influences that can be difficult to disentangle or predict, and can change very quickly. However, existing tools and analyses from political science and other disciplines<sup>2,4-7,27-32</sup> can help understand, manage, and navigate these forces.

## METHODS

This article examines two cases of priority setting in which ethical and political factors were reflected explicitly in the final decisions. That is, the decision problems were not solvable by reference to technical approaches alone and ethical and political judgments were made in addition. We explore the possible lessons that can be learned but do not suggest that they are generalizable to all contexts. Nevertheless, we contend that these cases are a helpful introduction, for policy

makers and others, to the roles of ethical and political considerations in priority setting.

The cases in this study are examples of priority setting under the national health benefit plans of Thailand and England. The screening for HLA-B\*1502 as a biomarker for severe hypersensitivity induced by carbamazepine in Thailand was selected because it is an example of how ethical considerations can be incorporated into the priority-setting process. It exemplifies a challenge that frequently arises in technology appraisals of interventions: how to make a decision when the technical evidence suggests different clinical and cost-effectiveness outcomes for different patient groups. Such scenarios raise ethical questions of whether to treat the groups the same or differently.

The CDF in England was selected because it exemplifies priority setting by political processes, which, in the view of some analysts,<sup>36</sup> undermined important technical and ethical considerations. The future of the CDF is still unfolding, but given the controversy the creation of the CDF has caused and the issues that it raises, the case illustrates how public policy concerns such as media pressure and policy priorities such as addressing low cancer survival rates may lead to decisions that cannot be explained by reference to technical or ethical considerations alone.

## CASE STUDY: SCREENING FOR HLA-B\*1502 AS A BIOMARKER FOR SEVERE HYPERSENSITIVITY INDUCED BY CARBAMAZEPINE IN THAILAND

### Background

In Thailand, 67 million citizens are eligible for essential health care subsidized by three government schemes, namely, the Civil Servant Medical Benefit Scheme, the Social Security Scheme, and the Universal Coverage Scheme (UCS; covers three-fourths of the population). The National List of Essential Medicines has been adopted by these schemes as their pharmaceutical benefits package.<sup>37</sup> By this, access to all items on the list is warranted for people with clinical conditions as indicated for particular drugs. For most indications, drugs of first choice and alternatives are listed according to the safety, clinical effectiveness, and cost-effectiveness; physicians are expected to prescribe first-line drugs unless the patient does not respond well or cannot tolerate side effects. However, because all drugs have at least some undesirable effects and many are potentially hazardous, policy makers and prescribers face the continuous and difficult challenge of how to weigh the expected benefits versus the probability of harm.

This case study focuses on an essential drug, carbamazepine, which is recommended as first-line treatment for epilepsy and neuropathic pain.<sup>38</sup> The drug may induce severe adverse reactions including Steven-Johnson syndrome (SJS) and toxic epidermal necrosis (TEN) in some patients. Although SJS and TEN are life-threatening, the incidence of such reactions induced by carbamazepine in Thailand is only 0.27% in neuropathic pain patients and 0.33% in epilepsy cases.<sup>39</sup> Therefore, beginning the treatment of epilepsy and neuropathic pain with more expensive but safer second-line alternatives is regarded as inefficient practice.

An alternative to carbamazepine is sodium valproate for epilepsy and gabapentin for neuropathic pain. Drug expenditure per case per year of carbamazepine is 2,550 Thai Baht (THB),<sup>b</sup> sodium valproate is 13,930 THB, and gabapentin is 11,740 THB. In addition, lifetime treatment cost per case (including drug cost, treatment cost for its adverse reactions, and direct non-medical care costs) when prescribing carbamazepine is 19,000 THB for treatment of neuropathic pain and 42,000 THB for epilepsy, sodium valproate 84,000 THB, and gabapentin 36,000 THB. The probability of severe adverse effects induced by sodium valproate and gabapentin is approximately 0.04%.<sup>c</sup> Because the publicly funded coverage policies are guided by three primary considerations—that is, population-level health outcomes, value for money, and financial implications at the societal level<sup>40</sup>—carbamazepine is listed as the medicine of first choice for the two indications in the benefit package and clinical practice guidelines.<sup>41,42</sup>

Recent development in biogenetics has resulted in an invention to predict the likelihood of drug-induced hypersensitivity in patients. Because the presence of a human leukocyte antigen, HLA-B\*1502, is strongly associated with carbamazepine-induced SJS and TEN, screening for such an antigenic allele can help identify individuals with high risk.<sup>43</sup> In the case of a positive test result, carbamazepine's alternative will be prescribed. In 2013, the HLA-B\*1502 screening test was proposed to be subsidized by the UCS.

As requested by the UCS authority, the National Health Security Office (NHSO), an assessment of the proposed intervention was conducted by an independent health technology assessment (HTA) institution, the Health Intervention and Technology Assessment Program. The findings suggested that screening for HLA-B\*1502 in Thailand is cost-effective when carbamazepine is prescribed to patients with neuropathic pain and cost ineffective in epilepsy treatment.<sup>d,44</sup> Because cost-effectiveness is a major criterion for coverage decisions, the screening test should have been provided to neuropathic patients only. However, because the UCS considered ethical reasons, including treating similar

cases in the same way and avoiding inconsistency in prescribing guidelines for carbamazepine to the two groups of patients,<sup>45</sup> the UCS subsidizes the screening in epilepsy cases as well. The decision makers' argument was that the risk and severity of carbamazepine-induced adverse reactions are identical in both groups of patients.

## Discussion

Although key stakeholders such as health providers, patient organizations, and health products industry continue to request that the NHSO issue explicit criteria for its benefit coverage, the policy authority keeps it flexible. This does not mean that UCS decisions are made without direction. In 2009, the NHSO instigated a program to ensure systematic, transparent, participatory, evidence-based technology appraisal, whereby value for money and budget implication are major concerns.<sup>40</sup> In practice, however, the decisions on particular interventions do not always conform to the two criteria, because other elements such as financial risks for the poor (if life-saving interventions are not covered in the UCS), program feasibility, and equity in access to related services across subpopulations may be considered more important.<sup>46</sup>

The Subcommittee for UCS Benefit Package Development agreed to cover the screening test for patients with neuropathic pain and epilepsy because this policy conformed to the equity principle and helped avoid inconsistency in treatment provision to the two groups of beneficiaries.<sup>44</sup> The decision suggests a view that although subsidizing the test in epileptic patients is not a cost-effective option, selectively withholding such a clinically effective intervention, which reduces the chance of severe side effects, is ethically unjustified. From an ethical perspective, omitting the screening test can be seen as leaving the patients to face the preventable life-threatening drug reactions and offering inequitable access to the life-saving intervention. The Subcommittee's decision indicates a high regard for the key principle of equal treatment (horizontal equity). Patients have the same risk of side effects and should be given equal changes to have them prevented. If, on the other hand, the principle of vertical equity applies, the two groups are equal in most respects, except that one group is more costly to screen and treat than the other. According to the principles and criteria outlined in Box 1, cost is a relevant difference and the two groups need not be treated equally. Therefore, in this case, reasonable people may disagree and fair processes may be helpful to resolve the issue.

This case study also highlights the importance of articulating reasons in a transparent way when making decisions in health priority setting. In the UCS, where explicit coverage decision criteria are lacking, decision makers need to provide the public with the reasons and justifications for covering or rejecting each intervention. The UCS's accountability

involves accountability for allocating public resources to ensure equitable access to standard health services among Thai citizens, and efficiency and financial sustainability of the health system must be secured.<sup>47</sup> Because there may be legitimate disagreement about ethical choices, policy authorities need to make the decision-making process transparent and participatory.<sup>48</sup> In particular, when cost-ineffective interventions are adopted, the rationale and related information including perspectives of stakeholders involved in the deliberation should be accessible in public domain. In our analysis, the UCS model of health priority setting, which is not strictly based on value for money, is accepted among stakeholders because efficiency is not the only goal of universal health coverage.<sup>49,50</sup>

## CASE STUDY: THE CANCER DRUGS FUND

### Background

In England, NICE makes recommendations on whether new pharmaceutical products should be made available in routine practice of the National Health Service (NHS). NICE uses ICERs to express the additional costs of new treatments in comparison to current alternatives and examines them in relation to the clinical benefits.<sup>51</sup> The clinical benefits are expressed in QALYs (quality-adjusted life years).<sup>e</sup> The threshold for new drugs to be recommended on the NHS is an ICER of £20,000–£30,000 per QALY.<sup>51</sup> In addition to the use of these clinical and cost-effectiveness measures, NICE has developed guidelines for making social value judgments and for considering so-called end-of-life criteria.<sup>10,52</sup> Drugs that are above the QALY threshold may be recommended if considerations such as social value judgments or end-of-life criteria apply. A consideration of end-of-life criteria is included in the majority of appraisals of cancer drugs even though not all of them meet the criteria.<sup>f</sup> Positive recommendations by NICE are binding, meaning that the treatments in question have to be made available on the NHS.

The CDF in England was established by the Conservative–Liberal coalition government in 2010. It was set up as a ring-fenced fund—meaning that the resources allocated to the CDF cannot be spent on other services—through which cancer patients can access cancer medicines that had not yet been evaluated by NICE or that had not been recommended by NICE. The CDF started with a budget of £200 million, which has since been increased on several occasions, first to £280 million and most recently to £340 million for 2015/2016 because of overspending in the past years.<sup>54</sup> To date, the total cost of the CDF was £968 million and the overspend in budget for the year 2014–2015 was 48%.<sup>55</sup> In addition,



74,380 patients have received access to drugs via the CDF since 2010.<sup>55</sup>

The CDF was intended as a temporary measure until a system of value-based pricing was established. This was to be an approach in which the NHS, with support of organizations like NICE, assessed the value of a drug and in which the price was to reflect this value. However, this new approach never materialized. The leading organization of the NHS, NHS England, has recently published proposals that would align the CDF more with NICE. Although the public consultation is ongoing, the CDF could become a managed access scheme as of April 2016, with NICE holding a major role in deciding which drugs will be available via the CDF.<sup>56,57</sup>

## Discussion

The creation of the CDF caused some bewilderment in the research and health care communities.<sup>36</sup> Critics of the CDF argue that it does not address the challenge of low cancer survival rates because it does not address the problem of waiting times for diagnostics and there is not a convincing case for why cancer patients should be privileged over other patient groups by having access to a ring-fenced drugs fund. Observers have also suggested that the CDF undermines the work of NICE,<sup>58</sup> leading to two parallel decision-making processes for new cancer drugs. The CDF has also been described as playing into the hands of powerful lobbies such as the pharmaceutical industry<sup>59</sup> and the cancer charities.

The above criticisms reflect the technical, ethical, and political aspects of priority setting. The argument that the CDF does not address the length of waiting times for diagnostic procedures reflects the view that more technical forms of evidence should inform priority setting. From an ethical perspective, one might argue that the CDF violates the principle of impartiality—because it is partial to the needs and concerns of cancer patients only—and raises questions with regard to the principles of fair distribution of resources and health maximization for all patient groups. On the other hand, by taking account of disease severity, ethical frameworks may allow for an ethical justification for the establishment of the CDF. However, for such a justification to be valid, the same ethical considerations should apply to other patients groups where severity of disease or health loss is substantial, as in the case of multiple sclerosis, for example.

Though the CDF raises important ethical and technical questions, the CDF exemplifies the influence of the political realm. The lower cancer survival rates compared to other European countries were framed as the main reason for the

creation of the CDF. Moreover, the political decision to continue the CDF was framed as a matter of saving and extending lives, a frame that is difficult to challenge in the public domain. Upon announcing the extension of the CDF in 2013, Prime Minister David Cameron said, “When I became Prime Minister three years ago, many patients with rare cancers were being denied lifesaving treatments. That is why we created the Cancer Drugs Fund, it is why we are extending it. [. . .]”<sup>60</sup>

NICE had already responded to public and political pressure by introducing end-of-life criteria. These criteria permit a higher cost-effectiveness threshold when drugs provide a valuable extension of life at the end of life, even if this extension may be marginal in some cases,<sup>53</sup> but even then some cancer drugs were not considered sufficiently cost-effective. The Coalition prioritized funding for cancer patients over other patients based on what they perceived as politically necessary. Faced with recurring negative headlines about NICE denying effective treatments to patients and England’s low cancer survival rates, policy makers are prone to go for politically opportune options to be seen to be “doing something.”<sup>61</sup> As one media outlet put it: “[. . .] the fund had the political benefit of defusing damaging arguments that have arisen when officials have denied access to expensive cancer treatment [. . .] on cost–benefit grounds.”<sup>62</sup>

Observers have argued that in establishing the CDF, the Coalition questioned the current process of priority setting, putting the future of NICE on the political agenda.<sup>58</sup> However, this does not seem to be the case because the government continues to provide strong support for the institution, indeed securing its future by enshrining its existence in the new NHS legislation.<sup>63</sup> This suggests that the creation of the CDF is another indication that in health priority setting, technical, ethical, and political judgments need to be considered alongside each other.

Given the existence of NICE as an HTA organization in England, the creation of the CDF can be interpreted as an expression of political forces that could not be fully managed by even a very robust HTA agency. The political salience of the future of the CDF is highlighted by the previously outlined changes proposed for the fund.<sup>56,57</sup> Despite these maneuverings, the challenge of denying access to cancer drugs when they are available elsewhere has still not been resolved. The proposed new approach is being watched closely by all stakeholders. As such, the CDF illustrates that political factors such as the need to address public opinion, unsatisfactory performance in key health areas, and the appeal of offering a compelling public narrative can lead to policy choices that may diverge from technical evidence and ethical judgments.

## CONCLUDING OBSERVATIONS

In this article we considered two cases of priority setting in hopes of illuminating some of the challenges that can arise when different analytic methods suggest different courses of action. Although an examination of only two cases cannot provide definitive evidence on the broader questions we raise, we nonetheless believe that our investigation provides a reasonable basis for advancing four observations about the priority-setting process. We furnish these observations in the hopes that they will be useful to policy makers considering how to strengthen or extend priority-setting processes.

1. **Different Methods Can Produce Different Recommendations:** The cases discussed in this article show that technical, ethical, and political considerations are all very important and may each recommend divergent courses of action. Similarly, formal priority-setting institutions may generate recommendations that are contested through broader political processes. The cases we present here show some of the complexity of priority setting and illustrate some of the diverse influences that shape decisions.
2. **Robust Processes Are Essential:** There is no absolute standard for setting priorities or weighting different types of evidence when they conflict, meaning that the most appropriate choice depends on a robust process for making decisions. In our opinion, these observations highlight the need for mechanisms to generate and consider each type of evidence and the need for mechanisms that can adjudicate differences between them; for instance, by creating agreement on an order of importance for political, ethical, and technical factors or by establishing institutions or processes to do so.
3. **Priority Setting is Inherently Political:** We began this article by observing that priority setting concerns who gets what, which is one definition of politics. We propose that if priority setting is inherently political, then its outcomes necessarily reflect political influences. In this light, political factors are the easiest to incorporate in priority setting because they are a function of existing political processes. By contrast, neither ethical nor technical factors are included by definition. The inclusion of technical and ethical factors can be challenging because it requires the construction of political visibility for these factors, which is not necessarily present in any given setting. We hypothesize that ethical factors have some intuitive political weight because they depend on values and judgments that are widely shared. We further speculate that technical factors can be more challenging to assert politically because typically they

depend on calculations accessible only to experts. In this light, we propose that priority setting can be considered usefully as the construction of processes to give political weight to ethical and technical factors.

4. **Transparency Can Help Build Support:** Even the term “priority setting” conveys a sense of the rationing conflict that underpins the need to choose some interventions or actions at the expense of some others. The cases we examined suggest that transparency about the trade-offs of different choices is an important ethical requirement and a potentially valuable means of building political support because it promotes participation and clarifies the implications of different choices.

## DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

No potential conflicts of interest were disclosed.

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## NOTES

- [a] For a more detailed discussion of these criteria, see Norheim et al.<sup>20</sup>
- [b] A purchasing power parity (PPP) dollar is 17.505 THB in 2011.

- [c] Based on experts' estimation because local data in Thailand are not available.
- [d] In Thailand, the cost-effectiveness threshold, endorsed by the UCS manager, is 160,000 THB per QALY gain; the incremental cost-effectiveness ratio when HLA-B\* screening test is provided to patients with neuropathic pain and epilepsy is 130,000 THB per QALY gain and 220,000 THB per QALY gain, respectively. The difference in value for money of introducing the screening test between the two indications is mainly driven by the cost of carbamazepine's alternatives: gabapentin is 11,740 THB per year and sodium valproate is 13,930 THB per year. The costs of alternative drugs are included in the cost-effectiveness analysis of the screening test, because providing screening intervention alone, without replacing carbamazepine with alternative drugs, cannot yield the desirable health outcome.
- [e] For a detailed explanation of NICE's methodology, see NICE.<sup>51</sup>
- [f] A detailed discussion of the end-of-life criteria is beyond the scope of this article. For more details, see NICE's guidelines.<sup>53</sup>
- [g] The attractiveness of the CDF policy to politicians is further underlined by the Labour Party's 2015 election campaign pledge to maintain the CDF, albeit in an adjusted format, in case it won the general election.<sup>61</sup>

## REFERENCES

- [1] Lasswell HD. Politics: who gets what, when, how. New York: Whittlesey House; 1936.
- [2] Roberts M, Hsiao W, Berman P, Reich M. Getting health reform right: a guide to improving performance and equity. New York: Oxford University Press; 2004.
- [3] Coulter A, Ham C, eds. The global challenge of health care rationing. Buckingham, UK: Open University Press; 2000.
- [4] Bump JB, Reich MR, Johnson AM. Diarrhoeal diseases and the global health agenda: measuring and changing priority. Health Policy Plan 2012; 28(8): 799-808.
- [5] Gilson L, Erasmus E, Borghi J, Macha J, Kamuzora P, Mtei G. Using stakeholder analysis to support moves towards universal coverage: lessons from the SHIELD project. Health Policy Plan 2012; 27(Suppl 1): i64-i76.
- [6] Shiffman J, Beer T, Wu Y. The emergence of global disease control priorities. Health Policy Plan 2002; 17(3): 225-234.
- [7] Reich MR. The politics of agenda setting in international health: child health versus adult health in developing countries. J Int Dev 1995; 7(3): 489-502.
- [8] Coulter A, Ham C, eds. The global challenge of health care rationing. Buckingham: Open University Press; 2000.
- [9] Kanavos P, Nicod E, van den Aardweg S, Pomedli, S. The impact of health technology assessments: an international comparison. Euro Observer: Health Policy Bull Eur Observ Health Syst Policies 2010; 12(4): 1-17.
- [10] Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. BMJ 2004; 329 (7459): 224-7.
- [11] Coulter A, Ham C, eds. The global challenge of health care rationing. Buckingham: Open University Press; 2000.
- [12] Kieslich K. Paradigms in operation: pharmaceutical benefit assessments in England and Germany. 2015. Available at [http://discov.ery.ucl.ac.uk/1463556/1/PhD\\_Thesis\\_K\\_Kieslich\\_17.03.2015.pdf](http://discov.ery.ucl.ac.uk/1463556/1/PhD_Thesis_K_Kieslich_17.03.2015.pdf) (accessed 23 September 2015)
- [13] Daniels N. Health-care needs and distributive justice. Philos Public Aff 1981; 10(2): 146-177.
- [14] Daniels N. Just health care. New York: Cambridge University Press; 1985.
- [15] Kamm FM. Equal treatment and equal chances. Philos Public Aff 1985; 14(2): 177-194.
- [16] Williams A. Ethics and efficiency in the provision of health care. In: Philosophy and medical welfare, Bell M, Mendus S, eds. Cambridge: Cambridge University Press; 1988; 111-126.
- [17] Menzel PT. Strong medicine. The ethical rationing of medical care. New York: Oxford University Press; 1990.
- [18] Norheim OF. Clinical priority setting. BMJ 2008; 337(7675): a1846.
- [19] Brock D, Wikler D. Ethical issues in resource allocation, research, and new product development. In: Disease control priorities in developing countries, 2nd ed., Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, Prabhat J, Mills A, Musgrove P, eds. New York: Oxford University Press and The World Bank; 2006; 259-270.
- [20] Norheim OF, Baltussen R, Johri M, Chisholm D, Nord E, Brock DW, Carlsson P, Cookson R, Daniels N, Danis M, et al. Guidance on priority setting in health care (GPS Health): the inclusion of equity criteria not captured by cost-effectiveness analysis. Cost Eff Resour Alloc 2014; 12: 18.
- [21] World Health Organization. Making fair choices on the path to universal health coverage. Final report of the WHO Consultative Group on Equity and Universal Health Coverage. 2014. Available at [http://apps.who.int/iris/bitstream/10665/112671/1/9789241507158\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/112671/1/9789241507158_eng.pdf?ua=1) (accessed 23 September 2015)
- [22] Rawls J. Political liberalism. New York: Columbia University Press; 1993.
- [23] Holm S. The second phase of priority setting. Goodbye to the simple solutions: the second phase of priority setting in health care. BMJ 1998; 317(7164): 1000-1002.
- [24] Norheim OF. Healthcare rationing—are additional criteria needed for assessing evidence based clinical practice guidelines? BMJ 1999; 319(7222): 1426-1429.
- [25] Daniels N, Sabin JE. Setting limits fairly: learning to share resources for health, 2nd ed. Oxford: Oxford University Press; 2008.
- [26] Daniels N. Just health: meeting health needs fairly. Cambridge: Cambridge University Press; 2008.
- [27] Reichenbach L. The politics of priority setting for reproductive health: breast and cervical cancer in Ghana. Reprod Health Matters 2002; 10(20): 47-58.

- [28] Reich MR. The politics of health sector reform in developing countries: three cases of pharmaceutical policy. *Health Policy* 1995; 32(1–3): 47–77.
- [29] Jacob L, Marmor T, Oberlander J. The Oregon health plan and the political paradox of rationing: what advocates and critics have claimed and what Oregon did. *J Health Polit Policy Law* 1999; 24(1): 161–180.
- [30] Klein R, Redmayne S. Patterns of priorities. A study of the purchasing and rationing policies of health authorities. Bath: University of Bath, Centre for the Analysis of Social Policy; 1994.
- [31] Klein R, Day P, Redmayne S. Managing scarcity. Priority setting and rationing in the National Health Service. Buckingham: Open University Press; 1996.
- [32] Ham C. Tragic choices in health care: lessons from the child B case. *BMJ* 1999; 319(7219): 1258–1261.
- [33] Mossialos E, Walley T, Mrazek M. Regulating pharmaceuticals in Europe: an overview. In: *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, Mossialos E, Mrazek M, Walley T, eds. Maidenhead: Open University Press; 2004; 1–38.
- [34] Walker P, Batty D. Patients protest after kidney cancer drugs rejected. 2008. Available at <http://www.theguardian.com/society/2008/aug/27/health.cancer> (accessed 20 July 2014)
- [35] Klein R. Dimensions of rationing: who should do what? *BMJ* 1993; 307(6899): 309–11.
- [36] Chamberlain C, Hollingworth W. Where is the evidence for the existence of the Cancer Drugs Fund? *BMJ* 2014; 349: g5901.
- [37] Teerawattananon Y, Tritasavit N, Suchonwanich N, and Kingkaew P. The use of economic evaluation for guiding the pharmaceutical reimbursement list in Thailand. *Z Evid Fortbild Qual Gesundheitswes* 2014; 108(7): 397–404.
- [38] National Medicines Policy Committee. National list of essential medicines, B.E. 2556 (A.D. 2013). Bangkok, Thailand: National Medicines Policy Committee; 2013.
- [39] Drug Information Center. Adverse drug reactions. Bangkok, Thailand: Chulalongkorn Hospital; 2015.
- [40] Mohara A, Youngkong S, Velasco RP, Werayingyong P, Pachanee K, Prakongsai P, Tantivess S, Tangcharoensathien V, Lertiendumrong J, Jongudomsuk P, et al. Using health technology assessment for informing coverage decisions in Thailand. *J Comp Eff Res* 2012; 1(2): 137–146.
- [41] Thailand Association for the Study of Pain. Clinical practice guideline for neuropathic pain. Bangkok, Thailand: Thailand Association for the Study of Pain; 2008.
- [42] The Epilepsy Society of Thailand. Clinical practice guidelines for epilepsy. Bangkok, Thailand: The Epilepsy Society of Thailand; 2010.
- [43] Lim K, Kwan P, Tan C. Association of HLA-B\*1502 allele and carbamazepine induced severe adverse cutaneous drug reaction among Asians, a review. *Neurol Asia* 2008; 13(1): 15–21.
- [44] Rattanavipapong W, Koopitakkajorn T, Praditsithikorn N, Mahasirimongkol S, Teerawattananon Y. Economic evaluation of HLA-B\*1502 screening for carbamazepine-induced severe adverse drug reactions in Thailand. *Epilepsia* 2013; 54(9): 1628–1638.
- [45] Subcommittee for Benefit Package Development. Meeting minutes, 19 November 2014. Nonthaburi, Thailand: National Health Security Office; 2014.
- [46] Tantivess S, Pérez Velasco R, Yothasamut J, Mohara A, Limprayoonyong H, Teerawattananon Y. Efficiency or equity? Value judgments in coverage decisions in Thailand. *J Health Organ Manag* 2012; 26(3): 331–342.
- [47] National Health Security Act. B.E. 2545 (A.D. 2002).
- [48] Tantivess S. Social and ethical analysis in health technology assessment. *J Med Assoc Thailand* 2014; 97(5): S81–S86.
- [49] World Health Organization. What is universal health coverage? 2015. Available at [http://www.who.int/health\\_financing/universal\\_coverage\\_definition/en/](http://www.who.int/health_financing/universal_coverage_definition/en/) (accessed 21 August 2015)
- [50] World Health Organization. The world health report 2000—health systems: improving performance. Geneva: The World Health Organization; 2000.
- [51] National Institute for Health and Care Excellence. Guide to the methods of technology appraisal 2013. 2013. Available at <https://www.nice.org.uk/article/pmg9/resources/non-guidance-guide-to-the-methods-of-technology-appraisal-2013-pdf> (accessed 16 November 2015)
- [52] Rid A, Littlejohns P, Wilson J, Rumbold B, Kieslich K, Weale A. The importance of being NICE. *J R Soc Med* 2015; 108(10): 385–389.
- [53] National Institute for Health and Clinical Excellence. Appraising life-extending, end of life treatments. 2009. Available at <https://www.nice.org.uk/guidance/gid-tag387/resources/appraising-life-extending-end-of-life-treatments-paper2> (accessed 28 October 2015)
- [54] NHS England. The Cancer Drugs Fund. 2015. Available at <http://www.england.nhs.uk/ourwork/pe/cdf/> (accessed 1 October 2015).
- [55] National Audit Office. Investigation into the Cancer Drugs Fund. 2015. Available at <https://www.nao.org.uk/wp-content/uploads/2015/09/Investigation-into-the-Cancer-Drugs-Fund1.pdf> (accessed 28 October 2015)
- [56] NHS England. Future of the Cancer Drugs Fund (CDF). 2015. Available at <https://www.england.nhs.uk/wp-content/uploads/2015/07/item-8-cancer-drug-fund.pdf> (accessed 27 October 2015)
- [57] NHS England. Cancer Drugs Fund consultation. 2015. Available at <https://www.engage.england.nhs.uk/consultation/cdf-consultation> (accessed 19 November 2015)
- [58] Jack A. Which way now for the Cancer Drugs Fund? *BMJ* 2014; 349(7974): g5524.
- [59] The Cancer Drugs Fund—benign or malignant? *The Economist*; 2015. Available at <http://www.economist.com/node/21640343/print> (accessed 25 August 2015)
- [60] Department of Health and Prime Minister's Office. Prime Minister announces £400 million package to boost research and treatment for cancer, and a new partnership to help map genomes [Press release]. 28 September 2013. Available at <https://www.gov.uk/government/news/thousands-of-patients-to-benefit-from-400-million-cancer-package> (accessed 27 August 2015)
- [61] Gallagher J. Labour pledges cancer therapy fund. 2014. Available at <http://www.bbc.co.uk/news/health-30385594> (accessed 29 October 2015)
- [62] Cook C. NHS England push to rein in cancer drug prices. 2014. Available at <http://www.bbc.co.uk/news/health-28938022> (accessed 28 August 2015)
- [63] Health and Social Care Act 2012 (2012).